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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,099	11/29/2001	Mary Mowrey-McKee	LP/V-31594/A	3645
31781	7590	01/27/2005	EXAMINER	
CIBA VISION CORPORATION PATENT DEPARTMENT 11460 JOHNS CREEK PARKWAY DULUTH, GA 30097-1556			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,099

Applicant(s)

MOWREY-MCKEE ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of remarks filed on September 17, 2004. Claims 1-8, 10-18 are pending. Claim rejection made under 35 U.S.C. § 112, second paragraph, is withdrawn in view of applicants' claim amendment. Claim rejections made under 35 U.S.C. §§ 102 (e) and 103(a) are withdrawn in view of applicants' remarks. New rejection is made.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 and 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuzuki (US 6121327).

Tsuzuki teaches a contact lens disinfecting solution comprising 1 ppm of PHMB (polyhexamethylene biguanide, an disinfecting agent); 1.5 % by weight of propylene glycol; 0.5 % by weight of Bis-Tris buffer, which is 1,3-bis(tris[hydroxymethyl]methylamino)propane meeting the formula and constituents of instant claims 1 and 19; 0.5 % by weight of EDTA salt, a chelating agent in instant claim 11. See Table 4 and 5, specimen no. 7 and 13. The pH of the solutions is said to be 7.2. See col. 1, lines 51 – 67; See instant claim 3. The specimen 13 also contains poloxamers, a surfactant. See instant claims 12 and 13. The solutions are said to contain NaCl, a tonicity agent, meeting instant claims 14 and 15. See col. 11, lines 66-67.

Tzusuki teaches that disinfectant is generally used in a concentration of 0.00001-0.1 w/v %, and preferably 0.00005-0.05 w/v % for exhibiting an effective disinfecting or preservative activity. See col. 4, line 60 – col. 5, line 6. The reference further teaches that at a concentration of the disinfectant below 0.00001 w/v %, no effective disinfecting or preservative activity will be obtained. See also col. 6, lines 3 – 9, which teaches that 0.1-10 ppm of PHMB is preferably used.

Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Based on the teaching of the general condition in the Tzusuki reference, examiner views that a routineer would have discovered the optimum or workable ranges by routine experimentation to formulate a preservative solution for contact lens.

Tzusuki also teaches that thickeners such as cellulose derivatives are used, since the contact lenses treated with the solutions containing the thickeners smoothly slide on palms and fingers when cleaning the lenses. See col. 4, lines 38 – 44. The reference further teaches that these cellulose derivatives do not adversely affect the properties of the contact lenses during long storage period. See col. 9, lines 1 – 20; See instant claims 16 and 17.

While the claim limitation requires the absence of polyol and Tsuzuki teaches the synergistic effect of the combined use of polyol and the bis-Tris compound, examiner takes the position that the reference still renders the claimed invention obvious. See col. 7, lines 9 – 50. It is well established in patent law that the use of patents as

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references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." See In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. See Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." See In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

In this case, Tsuzuki teaches that the bis-Tris compound is a well-known contact lens disinfectant. The fact that using bis-Tris compound without polyol is less effective does not change the fact that it is known. It would have been obvious to one of ordinary skill in the art at the time the invention was made that an aqueous solution comprising

bis-Tris as claimed would be an sufficiently effective contact lens disinfectant as taught by the reference.

Response to Arguments

Applicant's arguments filed September 17, 2004 have been fully considered but they are not moot in view of new grounds of rejection.

Conclusion

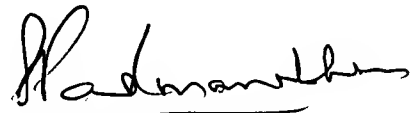
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner



**SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER**